



**Testimony
Committee on Homeland Security
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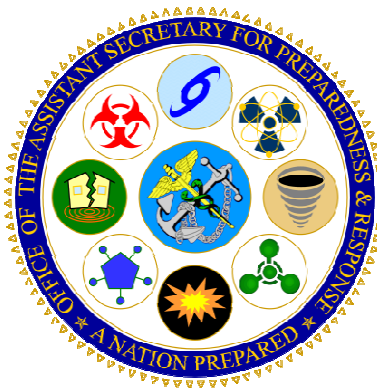
Protecting the Protectors: Getting MCMs to First Responders

Statement of

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Good afternoon Chairman Bilirakis, Ranking Member Richardson, and Members of the Subcommittee. I am Mr. Edward Gabriel, the Principal Deputy Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). Thank you for inviting me here today, on behalf of HHS, to testify on protecting first responders.

Before I begin this afternoon, I want to mention that maintaining and supporting our State and local response capability is of particular personal significance to me. Before joining ASPR six months ago, I spent thirty years as a first responder. I began as an Emergency Medical Technician (EMT) then became a Paramedic working throughout the City of New York. I rose through the ranks to become a New York City Fire Department Emergency Medical Services System Assistant Chief and ultimately became the Deputy Commissioner for Planning and Preparedness in New York City's Office of Emergency Management. I was on the ground with other first responders prior to the collapse of the towers on September 11, 2001 and personally witnessed the heroism and sacrifices of our first responders. I have spent my career responding to emergencies. I understand the needs of first responders and I truly believe that what we in the Federal government are doing is making a difference in our Nation's preparedness and will continue to improve the lives of those doing the work on the ground.

This afternoon I'm going to talk to you about the unique role that HHS plays in protecting and supporting the Nation's first responder community and helping them become more resilient after tragedy strikes. Our strategic approach involves creating best practices for getting medical countermeasures to first responders quickly in a range of emergency situations; developing promising new products, tools and technologies to protect our first responders and giving them the tools needed to be successful; and integrating behavioral health into overall public health and medical preparedness, response, and recovery planning. First responders are defined as a diverse set of individuals (emergency medical services practitioners, firefighters, law enforcement, and HAZMAT personnel, the emergency management community, public health and medical professionals, skilled support personnel, emergency service and critical infrastructure personnel, certain other government and private sector employees, and individual volunteers assisting in response activities) who are critical to mitigating the potential catastrophic effects of public health emergencies. I'll talk about our new approaches to coordination where Federal, State, local, tribal, territorial and private sector partners comprise the "medical countermeasures enterprise" and come together to collaborate and plan the development and deployment of countermeasures. Our approach throughout this enterprise takes the whole system into account – from early research to deployment – and includes the needs of first responders. I'll also focus on the first responder

community not only in the context of medical, fire and police but also other critical human services and how you and I, our families, and those in our communities might also play critical roles in a first response. I hope to leave you today with a clear picture of our work in this area and our proactive strategies to continue progress. Our Nation's ability to respond to an emergency depends on truly collective approaches and a strong partnership with our State and local partners who have the primary role in those first critical moments when the speed and thoughtfulness of response translates into more lives saved.

Supporting and assisting our Nation's first responders is a top Federal priority; however, we all recognize that the act of first response occurs primarily at the State and local level. Therefore, we focus attention on empowering States and communities to prepare for and respond to emergencies as safely, effectively, and efficiently as possible. As we are all aware, when disasters strike it is the response from the local community during the minutes before and after the event that saves lives. Our communities need to be resilient and be able to respond quickly. Today, State and local communities are more resilient than ever before. Incidents including the tornadoes that touched down in Alabama and Missouri in 2011 and recent flooding in Louisiana demonstrated how State and local communities are able to respond during the initial stages of the public health emergency response with little to no need for Federal assistance. HHS' Hospital Preparedness Program (HPP) and Public Health Emergency Preparedness (PHEP) cooperative agreement programs support State and local resilience by funding preparedness activities and infrastructure at State and local public health and medical facilities. A Hospital Preparedness Program report entitled "From Hospitals to Healthcare Coalitions: Transforming Health Preparedness and Response in Our Communities," describes the achievements of our state partners in building healthcare preparedness across the nation, and illustrates how states have used the capabilities developed and funded through the program in both large and small incidents. One specific accomplishment detailed in this report is that more than 76 percent of hospitals participating in the HPP met 90 percent or more of all program measures for all-hazards preparedness in 2009. These activities promote community resilience and improve health outcomes following emergencies and disasters.

Despite HPP and PHEP investments, the financial realities we are all facing today continue to challenge our public health and medical infrastructure and, ultimately, communities' ability to be resilient. We are already witnessing a decline in the State and local public health workforce as a result of these fiscal constraints.

As good stewards of Federal resources, we must focus on developing tools and strategies for all-hazards which can be implemented in a range of emergencies.

If a chemical, biological, radiological, nuclear (CBRN) or emerging infectious disease incident were to occur, we might have a few minutes or hours, not days, to dispense medical countermeasures to treat first responders and their communities, depending on the nature, scope, and size of the event. We will need first responders on the ground as soon as possible to treat the health impacts of the event and maintain the safety and security of their communities. In the aftermath of an event we will rely on multiple modalities to protect first responders, including pre- and post-event treatments. This treatment strategy is central to many of our preparedness plans including those for anthrax, smallpox, influenza and other agents. For bacterial threats, antibiotics offer one of the best courses of action as vaccines can take days, weeks, or months to be effective unless provided to responders beforehand. For example, the CDC's Advisory Committee on Immunization Practices recommends a three-dose anthrax vaccination regimen, as a post-exposure prophylaxis, for responders following an event, in addition to antibiotics. While the first vaccine dose would be administered as soon as possible post-exposure, the second and third doses would be administered two and four weeks later. The vaccine is not immediately effective and is not fully protective until after that third dose. Antibiotics are an important part of treatment strategies to bridge time gaps by maximizing protection from vaccines post-exposure.

To provide a quick and effective response, first responders will need to receive the most effective treatments quickly. I am pleased to say that Federal partners are working better together to ensure that we have the best tools available to treat and respond effectively to public health and medical emergencies. Federal partners are collaborating via the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) – the overarching interagency convening body for medical countermeasure development, stockpile, and use. ASPR leads the PHEMCE, which brings together three primary HHS agencies—the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA)—along with four key interagency partners—Department of Homeland Security (DHS), Department of Defense (DoD), Department of Veterans Affairs (VA), and Department of Agriculture (USDA). Working together full-time, as an enterprise, we are coordinating, exchanging information, and learning from each other daily to optimize preparedness and response for public health emergencies. The PHEMCE is bringing together partners not only to identify and support the development of a number of novel medical countermeasures to protect first responders but to also identify and plan for the use and distribution of acquired products.

Today, HHS and other Federal partners are working to develop new tools with potential all-hazards adaptability to support and protect first responders. While

HHS does not lead first responder activities, we do have a critical and unique role in advancing promising approaches in response at the national level which can then translate into local use. One such approach in the development and pre-approval phases is the anthrax “medkit.” The anthrax medkits contain the antibiotic doxycycline along with instructions for appropriate use in the home. Upon approval, medkits would be available in advance of an emergency to particular groups such as first responders and their families. These medkits could be purchased directly, either by the first responders themselves or their employers. While further research is needed to ensure medkits can be safely stored in private homes without misuse, we are optimistic about this capability and its implications for first responder protection during a public health or medical emergency.

As you know, we have already seen success in the use of the medkit concept through pilot testing the national U.S. Postal Service (USPS) medical countermeasures dispensing program. Supporting implementation of actions described in Executive Order 13527, *Medical Countermeasures Following a Biological Attack*, HHS has invested \$10M since 2010 to support national Postal Model grants awarded to specific cities and jurisdictions throughout the country. The grants fund planning and exercises to incorporate USPS employee volunteers into community plans to deliver medical countermeasures after an anthrax bioterrorism attack. Under this model, volunteer USPS letter carriers receive pre-event antibiotics via a Home Antibiotic kit that they store in their homes; these are for themselves and household members. If a public health or medical emergency requiring medical countermeasures occurred, letter carriers and their household members would be instructed to begin taking their antibiotics. This would allow these USPS volunteers to perform their mission, as outlined in the National Postal Model, to deliver antibiotics as prescribed by their specific postal plans. Law enforcement officers accompany the letter carriers as they deliver the antibiotics to homes in predetermined ZIP codes. Since this program began, we have learned lessons from the various exercises and have improved future applications and planning guidance. Recently, HHS held a table-top exercise in Louisville, KY. A primary focus was determining the roles of law enforcement and postal workers in delivery of medical countermeasures under “real life” circumstances. HHS is planning another full-scale exercise in Minneapolis on May 5 to examine issues and implications for the delivery of countermeasures to approximately 40,000 households in four zip codes. As we analyze results, we will coordinate with our partners and incorporate best practices into similar applications.

As we work with our partner agencies to develop all-hazards tools to support first responders, we must also develop policy documents to guide efforts to protect first responders and their communities from an anthrax attack and other

emergencies. These interagency guidance documents will provide clarity and improve coordination to ensure that the needs of all responders are met before, during, and after an emergency. It is critical that strategies are developed before an event to ensure that the tools available for all responders are used to their maximum capacity.

In addition to developing the policies themselves, there will be implementation challenges, including monitoring recipients of pre-event vaccinations, and in the aftermath of an event, the immediate availability of adequate vaccine and the availability of resources to support vaccination in the midst of an ongoing event will need to be addressed. These challenges span the regulatory authorities and resources of several Federal agencies and departments, as well as those of our State and local partners. HHS is actively engaging with interagency partners to address these challenges and establish policies for the distribution of medical countermeasures to first responders, not just for anthrax, but for all potential hazards and threats. As such, the resulting guidance documents will be considered “living documents” in the sense that they will be refined as the evidence base is strengthened for determining exposure risk and the efficacy of protective measures and feedback is received from stakeholders. Even as we update existing guidance and disseminate new guidance, we will look forward to continuing dialogue with our stakeholders and partners in the first responder community.

We’ve done considerable work in developing novel approaches to get medical countermeasures to first responders quickly and coordinate at all levels of government to ensure that our first line of defense is protected in an emergency. However, we are also looking forward and developing new and better medical countermeasures to both protect first responders and the communities they live in, as well as improving their toolkit to treat those affected. In August 2010, HHS Secretary Sebelius released the Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs (MCM Review). The MCM Review examined the steps involved and made recommendations regarding the research, development, and regulatory approval of medications, vaccines, and medical equipment and supplies for a public health emergency. In implementing recommendations of the MCM Review, HHS has already made progress in improving the entire medical countermeasure pipeline – from early stage research and development to distribution.

As I mentioned earlier in my testimony, the PHEMCE is bringing together partners to identify and to support the development and deployment of a number of novel medical countermeasures to protect first responders. My office works

closely with HHS partners including NIH, CDC, and FDA to develop, procure, and stockpile medical countermeasures for CBRN threats as well as emerging infectious diseases, including pandemic influenza. We are now more prepared for a broad range of threats and emerging infectious diseases than at any point in our Nation's history. We have a robust pipeline of next-generation products – we have gone from having very few products in the medical countermeasure pipeline over the last decade to funding over 80 candidate products that, if successful, have the potential to transition to procurement contracts and inclusion in the SNS. These products include: an entirely new class of antibiotics; anthrax vaccine and antitoxins; a new smallpox vaccine and antivirals; radiological and nuclear countermeasures including candidates to treat the various phases of acute radiation syndrome; pandemic influenza countermeasures; and chemical antidotes. In many cases, these products represent the future for enhanced protection of first responders.

Since Project BioShield – the primary tool HHS uses to procure novel CBRN medical countermeasures for the SNS – was authorized in 2004, HHS has strengthened internal and external contracting mechanisms, and research and development pathways, and has incorporated lessons learned from past challenges. As my colleague at DHS will detail, there is much discussion about the pre-event vaccination of first responders against threats such as anthrax. However, the current vaccine regimen is burdensome as it requires five vaccinations over 18 months and annual boosters to produce immunity. We all agree that all responders have to be adequately protected, and if a decision is made to make anthrax vaccine available to them, it would help to have vaccines that require fewer immunizations. As part of its efforts to develop vaccines to protect the entire civilian population, HHS is currently investing in more than 20 programs for next generation anthrax vaccines, four of which have transitioned from early to advanced research and development. The programs have the potential to provide protective immunity with 3 doses of vaccine or less, are easier to administer, and have a decreased life-cycle cost due to lack of the cold chain requirement.

Funding for Project BioShield expires in 2013 and work to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA) is ongoing. The proposed legislation includes the reauthorization of appropriations for Project BioShield through 2018. Investing in development of medical countermeasures, novel approaches to response operations, and our public health infrastructure is critical in ensuring that adequate medical countermeasures are available for dispensing as soon as possible following the start of a public health incident. The reauthorization of PAHPA will support our work and will ensure we continue to have the tools necessary to respond.

As part of our strategic approach to encouraging innovation in medical countermeasure development, we are also developing new tools for all responders and a number of these efforts are already showing results. HHS is developing a next generation portable ventilator that will be lighter and less expensive making it easier and quicker to administer critical treatments. In 2007, HHS convened a blue ribbon panel of experts to review the state of ventilators in the market against the requirements for use in all-hazards preparedness. In September 2010, an advanced research and development contract was awarded to Newport Medical in California for design and development of a next-generation portable ventilator that is at a highly-affordable price point and that could be used with minimal training on a broad range of patients from neonates to adults. A prototype was developed by July 2011 and is currently being evaluated. The initial results are promising and the program is on schedule to file for market approval in September 2013.

As we develop medical countermeasures to respond to public health and medical emergencies we must not ignore the needs of first responders and their communities after an event. Community based responders are the first to arrive on the scene when an incident occurs and they remain in the community through recovery. A major event such as an aerosolized anthrax attack will require response and recovery activities long after the initial threat has passed. First responders will play a key role in these locally-led recovery efforts toward the restoration of public health and medical services. First responders are the backbone of our public health and safety infrastructure; by supporting them, we ensure that the human infrastructure remains intact throughout the response and recovery phases, and ready for the next emergency. Recovery is a part of preparedness, and the National Disaster Recovery Framework, released in September 2011, provides guidance to all levels of government, the private and nonprofit sectors, and individuals and families on activities they can undertake both pre- and post-disaster to plan for a successful recovery. HHS leads the Health and Social Services Recovery Support Function under that framework, and ASPR has established a Recovery Coordination Office to carry out those responsibilities and also leverage opportunities to incorporate recovery into on-going preparedness efforts. We have also supported innovation and continuous improvement in our efforts to support first responders and others during the recovery phase. Based on lessons learned in Hurricanes Katrina and Rita, HHS recognized the need for enhanced coordination of disaster-related healthcare, mental health and human services needs at all phases of response. Today HHS' Administration for Children and Families, in partnership with FEMA, administers the Federal Disaster Case Management Program, which provides disaster survivors with a single point of contact for accessing resources and services to address disaster-caused needs, and for developing and completing a personalized Disaster Recovery Plan. While they are not first responders in the traditional sense, our disaster case managers are on the ground in the aftermath

of a disaster providing support to their fellow responders and impacted individuals.

In addition to supporting officially-designated and trained first responders, we are also leveraging the Internet to supplement the first response. In particular, under the America Competes Act, we are issuing a "challenge" for development of a web-based application able to automatically deliver a list of the top-five trending illnesses from a specified geographic region in a twenty-four hour period. Under the envisioned program, data would then be sent directly to State and local health practitioners to use in a variety of ways, including building a baseline of trend data, engaging the public on trending health topics, serving as an indicator of potential health issues emerging in the population, and cross-referencing other data sources. The more we know and the earlier we understand emerging health trends, the better prepared we all are – including first responders – in providing treatment to affected individuals and limiting the impact of the event.

In conclusion, all of our investments and efforts come down to the same goals—building a resilient nation and saving lives when emergencies occur. This is true for all of us, whether in the Federal, State, local, tribal, territorial, or private sector. Before coming to ASPR, I was the Director of Global Crisis Management and Business Continuity for the Walt Disney Company. In this position I was responsible for the development and implementation of global policy, planning, and training to manage crises for The Walt Disney Company. I was also responsible for East and West Coast Medical and Emergency Medical Operations as well as the Walt Disney Studio's Fire Department. My work with Disney required development of strong and productive relationships with law enforcement, emergency management and intelligence services counterparts as well as private sector counterparts worldwide. Based on my experiences, meeting the needs of our first responders before, during and after an event is critical. We have made great strides toward building a robust enterprise to develop medical countermeasures and to quickly get them to people who need them. We are incorporating the clinical community into national preparedness systems and are preparing clinicians to treat patients affected by emergencies. We are collaborating with State and local partners to develop, exercise, and improve their response capabilities. All of our efforts will ensure the next public health or medical emergency is responded to in the best, most effective way possible. I look forward to working with you to ensure that this progress and our strategies for the future continue to prepare the Nation and save lives.

Thank you for the opportunity to testify before you today. I am happy to answer any questions you may have at this time.